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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,778	11/13/2001	Eric Hauser Kuhrts	68911-076	4731

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MIAMI, FL 33131

EXAMINER

MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
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1655

MAIL DATE	DELIVERY MODE
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02/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/008,778

Applicant(s)

KUHRTS, ERIC HAUSER

Examiner

Michael V. Meller

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1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-12, 14, 16 and 18-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Any rejection not reiterated is hereby dropped.

Election/Restrictions

The restriction requirement of record is maintained for the reasons of record. Claims 1-12, 14, 16, 18-27 are withdrawn since they are drawn to non-elected subject matter. The restriction requirement has already been made **FINAL** as noted by applicants.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the

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United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 13 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Newmark et al. (col. 1, lines 14-17, col. 3, lines 55-60, col. 4, lines 30-end, col. 6, lines 25-35) or Babish et al. (paragraphs 25, 33, 34).

The references each teach that hops are extracted with supercritical CO₂. As noted by FR 2590589 (already of record) it is noted that when hops are extracted with supercritical CO₂ iso-alpha acids are formed. Thus, when each of the references extracted hops with supercritical CO₂ they produced iso-alpha acids and as noted in the

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references each reference administered the hops extracts (which would include iso-alpha acids) to treat inflammation and pain which would clearly read on the claimed subject matter. Note also that Babish does explicitly mention iso-alpha acids at paragraph 34 such as isohumulone. Thus, providing further evidence that when the supercritical CO₂ is used, iso alpha acids are indeed formed.

The COX-2/COX-1 ratio is inherent to the composition of hops since iso alpha acids are also what applicant uses in their application to treat mammals. The extraction is done exactly as applicant's (using supercritical CO₂) thus the same ratio is inherently produced.

Applicant argues that mere CO₂ extraction does not produce iso alpha acids suitable for administration and then cites parts of the specification which talk about producing iso alpha acids from alpha acids. While this is quite interesting, it does not negate the fact that both references teach such CO₂ extraction which will inherently produce iso alpha acids as noted by Babish and also note that Babish clearly produced a product of iso alpha acids which is bioavailable, see paragraphs 34 and 47 of Babish.

Applicant argues that supercritical CO₂ extracts do not form iso alpha acids. Applicant relies on three pieces of information.

First, applicant argues that Verzele et al. allegedly teaches that by specifically distinguishing ethanolic extracts from supercritical CO₂ extracts that iso alpha formation may occur as part of an ethanol extraction process but does not occur during supercritical CO₂ extraction. The reference is inconclusive. Applicant is making this

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assumption. There is nothing in this reference to prove that iso alpha acids are not produced by supercritical CO₂.

Next, applicant turns to Barth-Haas to allegedly show that supercritical co₂ extracts do not contain isoalpha acids because they never mention isoalpha acids as being in a co₂ hops extract. This proves nothing because as shown by Babish, alpha acids routinely include isoalpha acids when being referred to in a list of ingredients. The statement in Barth-Haas that iso alpha acids are produced from co₂ hops extract does not mean that iso alpha acids are not produced from co₂ extracts, it further provides evidence that iso alpha acids are produced from co₂ extracts of hops.

Thirdly, the applicant argues that since the photoisomerization process can only be performed on the extracted alpha acid that this isomerization process is therefore one process step removed from the extraction process. This is not well taken. This provides no conclusion. There is no evidence that the above statement is true by applicant. It is only applicant's opinion that the photoisomerization process can only be performed on the extracted alpha acid. No evidence of this has been provided. Further, even if the evidence were provided, it is clear from FR 2590589 that the co₂ extraction clearly yields iso alpha acids.

Further, as noted in Babish in paragraphs 28, 33, 34, that it is clear that alpha acids include iso alpha acids. Further it is clear that such alpha acids are prepared by co₂ extraction.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newmark et al. (col. 1, lines 14-17, col. 3, lines 55-60, col. 4, lines 30-end, col. 6, lines 25-35) or Babish et al. (paragraphs 25, 33, 34).

The references each teach that hops are extracted with supercritical CO₂. As noted by FR 2590589 (already of record) it is noted that when hops are extracted with supercritical CO₂ iso-alpha acids are formed. Thus, when each of the references extracted hops with supercritical CO₂ they produced iso-alpha acids and as noted in the references each reference administered the hops extracts (which would include iso-alpha acids) to treat inflammation and pain which would clearly read on the claimed subject matter. Note also that Babish does explicitly mention iso-alpha acids at paragraph 34 such as isohumulone. Thus, providing further evidence that when the supercritical CO₂ is used, iso alpha acids are indeed formed.

The COX-2/COX-1 ratio is inherent to the composition of hops since iso alpha acids are also what applicant uses in their application to treat mammals. The extraction is done exactly as applicant's (using supercritical CO₂) thus the same ratio is inherently produced.

Applicant argues that mere CO₂ extraction does not produce iso alpha acids suitable for administration and then cites parts of the specification which talk about producing iso alpha acids from alpha acids. While this is quite interesting, it does not negate the fact that both references teach such CO₂ extraction which will inherently produce iso alpha acids as noted by Babish and also note that Babish clearly produced a product of iso alpha acids which is bioavailable, see paragraphs 34 and 47 of Babish.

In the event that the ratio of claim 13 is not inherent to the composition (which this examiner highly disagrees with for the above reasons) then it would have been at least obvious to one having ordinary skill in the art to purify the hops extract to such a ratio in an effort to optimize the desired results.

The result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of the components within the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

The applicants arguments here are the same as above thus the rebuttal is the same as above.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael V. Meller/

Primary Examiner, Art Unit 1655

Application Number**Application/Control No.**

10/008,778

**Applicant(s)/Patent under
Reexamination**

KUHRTS, ERIC HAUSER

Examiner

Michael V. Meller

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